CASE/0641/06/25

COMPLAINANT v FRESENIUS KABI

Allegations relating to promotion of a product prior to the grant of its marketing authorisation

CASE SUMMARY

This case was in relation to an 'ePoster' presented at a rheumatology congress held in the UK in 2025. The complainant alleged that the poster promoted Fresenius Kabi's biosimilar to denosumab, which had not yet received a marketing authorisation in the UK or EU.

The outcome under the 2024 Code was:

Breach of Clause 3.1	**Promoting a medicine prior to the grant of its marketing authorisation**
Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 11.1	**Promoting a medicine prior to the grant of its marketing authorisation**

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint about Fresenius Kabi was received from an anonymous, non-contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

> "I am submitting a complaint regarding the conduct of Fresenius Kabi at [a named rheumatology congress in the UK] in May 2025, specifically in relation to the display of an ePoster detailing data from the LUMIADE-3 trial for FK5518, a proposed biosimilar to denosumab. The product has not yet received a marketing authorisation in the UK or EU, yet Fresenius Kabi showcased clinical data, including efficacy, safety, and immunogenicity findings, in what appears to be a promotional context, including a call to action directing attendees to their exhibition stand. This conduct appears to be part

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of a coordinated pre-launch promotional strategy and breaches several clauses of the 2024 ABPI Code of Practice as detailed below.

1. Clause 3.1 – Promotion of Unlicensed Medicines
   - The ePoster included detailed results of the LUMIADE-3 randomized controlled trial for FK5518, including study design, primary and secondary endpoints, efficacy results, safety findings, and biosimilarity conclusions.
   - Although FK5518 was described as a "proposed biosimilar," the timing and detail of data presentation, particularly in a high-profile scientific setting so close to the expected launch, constitutes promotion prior to authorisation.
   - The phrase "Come see us at Stand 26", when presented alongside such data, further supports the interpretation that this was a promotional invitation to discuss or generate interest in an unlicensed product, in breach of Clause 3.1.
   - As per previous PMCPA rulings, displaying detailed data of an unlicensed medicine in a context that may influence prescribing is not permitted, regardless of whether it is presented in scientific format.

2. Clause 5.1 – Failure to Maintain High Standards
   - The use of a prescriber-focused scientific congress as a platform to share near-launch data on an unlicensed medicine demonstrates poor judgment and is inconsistent with the high standards expected under Clause 5.1.
   - There is a risk that HCPs may interpret this information as a signal of imminent availability or regulatory endorsement, which can lead to misleading clinical assumptions.
   - The lack of restraint in timing, tone, and messaging undermines trust in the responsible conduct of pharmaceutical companies.

3. Clause 8.1 – Certification of Promotional Material
   - The ePoster did not include any visible job code, approval statement, or certification marking, despite containing data and messaging that could be construed as promotional.
   - If Fresenius Kabi consider this ePoster to be promotional material, which it likely is, given its placement and content, it should have been certified under Clause 8.1.
   - The omission raises questions about whether this material was properly reviewed and approved prior to dissemination.

4. Clause 11.1 – Promotion Prior to Grant of Marketing Authorisation Clause 11.1 clearly states: "A medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply."
   - FK5518 has no such authorisation in the UK.
   - Presenting detailed clinical data alongside a call to engage with representatives is promotional activity prohibited under this clause.
   - This applies regardless of whether the term "proposed biosimilar" was used — the effect is still promotional.

5. Clause 12.1 – Provision of Prescribing Information
   - Clause 12.1 requires that all promotional materials include prescribing information or a link/QR code to it.

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- The ePoster did not contain prescribing information, nor a QR code or equivalent.
- If Fresenius Kabi considers this to be promotional material as the invitation to a stand and the data content suggest, then it is non-compliant with this clause.

Supporting Information:
Please see attached photographic evidence showing:

- All four slides of the ePoster, clearly presenting:
  - FK5518 as the subject product.
  - Detailed study design and methodology.
  - Quantitative efficacy and safety data.
  - Biosimilarity conclusions.
  - The prominent call to action: "Come see us at Stand 26."

Additionally, Fresenius Kabi has made public statements about the expected 2025 launch of FK5518, adding to the concern that this activity forms part of a coordinated pre-launch communication strategy. The timing, content, and context of this activity strongly suggest that Fresenius Kabi has breached Clause 3.1, Clause 5.1, Clause 8.1, Clause 11.1 and Clause 12.1 of the ABPI Code. I urge the PMCPA to investigate this matter thoroughly and take appropriate action."

When writing to Fresenius Kabi, the PMCPA asked it to consider the requirements of Clauses 2, 3.1, 5.1, 8.1, 11.1 and 12.1 of the 2024 Code.

FRESENIUS KABI'S RESPONSE

The response from Fresenius Kabi is reproduced below:

"We acknowledge receipt of your letter dated 26 June 2025, which was forwarded to us for response, regarding a complaint alleging, amongst others, the promotion of a medicinal product prior to grant of marketing authorisation at a Health Care Professionals' ("HCP") congress in the UK.

We strongly refute all allegations (i.e., alleged breaches of Clauses 3.1, 5.1, 8.1, 11.1, 12.1 and particularly of Clause 2 of the ABPI Code of Practice 2024 (the "Code")). Fresenius Kabi is fully aware of and in compliance with the restrictions on promoting a medicinal product prior to the grant of a marketing authorisation. We have strict policies and processes in place to ensure that all materials, both promotional and non-promotional, are reviewed, approved and certified by [details of medical signatory provided] (the "Signatory").

We respectfully submit that our sharing of clinical data concerning proposed biosimilar candidate FKS518 (a currently unlicensed medicine) at a UK medical congress did not constitute a breach of the Code. The Code prohibits the promotion of prescription-only medicines prior to the grant of a marketing authorisation. However, it does not prohibit the non-promotional dissemination of scientific information, including clinical trial data, when conducted in a responsible, factual, and balanced manner. The material being the subject of this complaint was presented in a scientific forum and to a professional audience. All information was clearly framed as scientific, data presented was accurate, fair, balanced, and capable of substantiation, and no claims were made

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that extended beyond the data. The investigational status of the product was explicitly disclosed, and no promotional materials, inducements, or comparative claims were included.

BACKGROUND

The [named rheumatology congress] (the Congress) is the largest, annual rheumatology congress in the UK. The 2025 congress, held in [named UK city] from [date–date] April, was attended by over 2000 HCP delegates. It featured plenary scientific sessions as well as oral and poster presentations of scientific research from academia and industry.

The material in question and subject of the complaint, was a digital poster presentation of the LUMIADE-3 clinical trial which detailed the Phase III clinical trial results of FKS518, a proposed biosimilar candidate (the "Poster"). The Poster was an encore presentation of a poster (comprising of the same clinical data) that was previously presented by our medical team at the American Society of Clinical Oncology (ASCO) congress in the USA in 2024.

The Congress was the first opportunity to submit the encore presentation of the Poster at a major rheumatology congress in the UK. The abstract was submitted to the [congress organisers] in October 2024 and accepted for oral and digital presentation in January 2025, with the intention of presenting the results at a *bona fide* scientific congress; transparently informing the scientific and medical community that Fresenius Kabi had completed a Phase III study and disclosing the data to encourage scientific discourse. The final digital Poster was submitted in early April 2025 and was presented by a Fresenius Kabi Medical Scientific Liaison ("MSL") during the Congress. The Poster contained purely scientific, factual (and non-promotional) information and was available to view on digital screens throughout the Congress and to HCP delegates who registered for online access. It was a '*...legitimate exchange of medical and scientific information during the development of a medicine and is not prohibited...*' under the Supplementary Information to Clause 3.1.

Fresenius Kabi's marketing authorisation application for FKS518 is under review by EMA and has not yet been granted. Consequently, it has also not yet been approved by the MHRA. As the biosimilar candidate FKS518 did not have a marketing authorisation, the Poster was examined and approved by the Signatory in line with the requirements of the Code. All other promotional materials at the congress were certified by the Signatory as required by the Code.

RESPONSE TO COMPLAINT

We would like to address each of the complainant's alleged breaches of the Code in turn.

1. Alleged breach of Clause 3.1 – Marketing Authorisation.

    a. As the complainant has correctly pointed out, the proposed biosimilar candidate FKS518 has not yet received a marketing authorisation and hence was only referred to by its internal product identifier (i.e. no brand

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names), with the explicit disclaimer that FKS518 was a "proposed biosimilar" rather than an approved medicinal product. The Poster contained only scientific, factual statements regarding the Phase III clinical study results of the LUMIADE-3 study. The Poster did not contain any promotional content or content discussing commercial and/or regulatory aspects (e.g., there were no references to regulatory submissions, launch dates, prices or brand names etc), but comprised only legitimate and permissible medical and scientific information, as permitted by the Code in the Supplementary Information to Clause 3.1.

b. Prior to its presentation at the congress, the Poster was reviewed and approved within our external materials approval system by our Signatory as a non-promotional item with the job code IE-NP-2500022 and a date of approval of 07 April 2025.
c. Further, there were no printed and/or digital materials relating or referring to denosumab's mechanisms of action or its related therapeutic uses at the congress stand. The congress stand only made reference to two other Fresenius Kabi products that already had marketing authorisation.
d. The briefing document for the Congress did not include any promotional messages relating to FKS518. Indeed, the briefing document created for the Congress did not make any reference to FKS518 except to inform the commercial team about the logistics relating to the presentation of the Poster and oral presentations at the congress. The commercial team were instructed that... '*For product information, refer to Medical or complete a medical information request form….*' if there was any product information required.
e. Any queries about the clinical study or the biosimilar candidate were directed to the medical staff at the meeting, logged as medical information requests and dealt with by the medical team. The medical staff were in attendance at all times.

In summary, with the evidence presented above, Fresenius Kabi strongly refutes the allegation that FKS518 was promoted prior to the grant of a marketing authorisation as alleged by the complainant and did not breach Clause 3.1 of the Code.

2. Alleged breach of Clause 5.1 – Failure to Maintain High Standards.

a. The complainant alleges that sharing clinical trial data on a proposed biosimilar demonstrated poor judgement and thus a failure to maintain high standards.
b. The sharing of the Phase III clinical trial data of the LUMIADE-3 study was for the purposes of sharing legitimate medical and scientific data on a proposed biosimilar to denosumab as permitted under the Code (Supplementary Information to Clause 3.1).
c. The proposed biosimilar FKS518 was only referred to insofar as the study results were factually presented on the Poster at the Congress. Such reference included the explicit disclaimer that FK5518 is a "proposed biosimilar" and at no time was there any mention of prospective/actual availability or approval timelines of the biosimilar

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candidate. FKS518 was not mentioned in any other materials (briefing documents or otherwise) to Fresenius Kabi employees or congress participants.

d. We also note that the PMCPA's own guidance acknowledges the importance of context, audience, and intent in determining whether an activity is promotional. Our intent was solely to contribute to scientific understanding and to engage in legitimate medical education, not to promote an unapproved product. Moreover, the clinical data presented on the poster was displayed exclusively at a scientific congress attended by healthcare professionals, who are accustomed to reviewing such data in this context. The assertion that an HCP would interpret the digital poster as '*…signal of imminent availability or regulatory endorsement...*' is unsubstantiated speculation on behalf of the complainant. Nothing presented in the Poster suggested imminent availability or regulatory endorsement of the proposed biosimilar product.
e. The Poster, congress stand, and briefing documents were all examined and certified as required by the Code, underpinning Fresenius Kabi's contention that stringent standards of compliance were upheld in ensuring all materials at the congress were compliant with the Code and applicable laws.

In summary, Fresenius Kabi strongly refutes the allegation that high standards were not maintained and maintain that there was no breach of Clause 5.1.

3. Alleged breach of Clause 8.1 – Certification of Promotional Material

a. The complainant alleges that there was no visible job code, approval statement or certification marking on the Poster.
b. As the Poster did not include any promotional material (and given that the biosimilar candidate to which it related was not approved), there was no requirement to have it certified under the Code.
c. Indeed, the Poster contained only scientific, factual information relating to the clinical trial of an investigational drug. It was part of a broader scientific exchange, consistent with the Code's recognition that the responsible sharing of clinical data, including for unlicensed products, is permissible when done appropriately and transparently.
d. In compliance with the Supplementary Information to Clause 8.3, the Poster was assigned a job code and examined and approved by our Signatory and in accordance with our internal processes.
e. Furthermore, all content available at the stand was certified in accordance with Clause 8.
f. Any discussion of investigational products was conducted in a factual, balanced, and non-promotional manner, consistent with the requirements of the Code and as evidenced in the conference briefing document.
g. The job bag number was not added to the Poster, it being non-promotional material, as there is no Code requirement to do so.

In summary, Fresenius Kabi refutes the allegation that the Poster was not certified under Clause 8.1 of the Code. The Poster was reviewed and approved

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as non-promotional material. However, it is not a Code requirement to add the job code to this non-promotional Poster and, therefore there was no breach of Clause 8.1 of the Code.

4. Alleged breach of Clause 11.1 – Promotion prior to grant of marketing authorisation.

    a. The complainant alleges that Fresenius Kabi had promoted the biosimilar FKS518 prior to the grant of marketing authorisation.
    b. As evidenced above, the sole intention of the submission of the Poster to the medical congress was to share scientific data pertaining to a Phase III clinical trial (LUMIADE-3) with HCPs. The statement '*Come and see us at Stand 26*' was used in a non-promotional context to provide logistical information and facilitate professional engagement at a scientific congress, in line with the Code's provisions on meetings and events. This phrase was used solely to direct HCPs with scientific/medical inquiries to where appropriately trained medical staff were, who were present at all times and facilitate discussions regarding the scientific data presented in the Poster.
    c. This neutral, directional phrase did not include any product claims, inducements, or promotional messaging. There was no reference to approval timelines, launch dates, prices, brand names or availability, or any commercial information available at the congress stand, as evidenced by the briefing document. The phrase served a practical and administrative function, not a promotional one.
    d. Further, as mentioned above, the commercial staff were briefed to strictly direct any queries to the onsite MSLs or record it as a medical information request. Indeed, the briefing document contains specific instructions that '*For product information, refer to Medical or complete a medical information request form*'.
    e. Moreover, there were no promotional materials or messages at the congress stand with regards to FSK518 or any reference to denosumab or it's mechanisms of action, as evidenced by the stand approval and the briefing document. No product/brand names were used. No regulatory or commercial information was discussed and no statements aimed at promoting the use or prescription of the biosimilar candidate FKS518 were made.

    In summary, Fresenius Kabi strongly refutes the allegation that it promoted FKS518 prior to the grant of marketing authorisation and maintain that there was no breach of Clause 11.1.

5. Alleged breach of Clause 12.1 – Provision of Prescribing Information.

    a. The complainant alleges that Fresenius Kabi failed to add 'required' prescribing information to FKS518 or a related QR code to the Poster.
    b. However, as FKS518 had not been granted marketing authorisation by EMA or the MHRA (nor had a price been agreed with the Department of Health), prescribing information could not be generated as required by Clause 12.2 of the Code for approved products.

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c. Furthermore, mandatory information (such as prescribing information) can only reasonably be added once a product has regulatory approval and content serves promotional purposes. As the Poster contained only scientific information and did not contain any promotional material, there was no regulatory basis for including prescribing information or a QR code with the Poster.

In summary, Fresenius Kabi submits that as the Poster was not promotional material, there would be no requirement to include prescribing information. Furthermore, as the biosimilar candidate FKS518 had not received marketing authorisation at the time of the Poster presentation, nor had prices been agreed with the Department of Health, there was clearly no possibility to create Prescribing Information for FKS518. Therefore, Fresenius Kabi submits that there was no breach of Clause 12.1.

6. Alleged breach of Clause 2 – Upholding Confidence in the Industry

   a. We note that the PMCPA has raised Clause 2 as a potential breach at case preparation stage. For the reasons set out above, Fresenius Kabi believe that there have been no breaches of the Code as alleged, and as a result the Poster would not have breached Clause 2 of the Code.

CONCLUSION

Fresenius Kabi strongly refutes all the allegations of breaches of Clauses 3.1, 5.1, 8.1, 11.1 and 12.1 of the Code by the complainant and we have submitted evidence to substantiate our position. Furthermore, Fresenius Kabi submits that we have not breached of Clause 2 as raised by the PMCPA.

The clinical data shared in the Poster was purely investigational and non-promotional. All materials, including the Poster, congress stand, and briefing documents were appropriately examined or certified as per requirements of the Code by the registered Signatory. There is no evidence to suggest any promotion of biosimilar candidate FKS518 prior to grant of marketing authorisation in any of the materials in question.

It is clear from our submission that this was a legitimate exchange of scientific information, in a scientific forum to a professional audience, with the sole intent of contributing to the scientific discourse and advancing medical knowledge.

Our conduct aligns with the principles of the Code; supporting high standards in the pharmaceutical industry while enabling the responsible sharing of information that may ultimately benefit patient care.

Considering the above, we respectfully maintain that our conduct was consistent with both the letter and spirit of the Code, and we request that the Panel finds no breach in this matter.

Thank you for the opportunity to respond to and refute the allegations as put forward by the complainant and the PMCPA

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We look forward to hearing from you."

FURTHER INFORMATION FROM FRESENIUS KABI

Fresenius Kabi's response to a request from the Panel for further information is reproduced below:

"We can confirm the following points to support the Panel in its investigation into the allegations.

1. Clarification of any points in which the Panel's understanding is incorrect in any way

   [Bullet points copied from the Panel's letter to Fresenius Kabi in which the Panel presented its current understanding, based on the company's original response and the photographs provided by the complainant:]
   - The ePoster, submitted to the congress by Fresenius Kabi, was available to view on digital screens throughout the congress and to HCP delegates who registered for online access.
   - The ePoster at issue consisted of four slides accompanied by a voiceover delivered by an MSL (effectively a pre-recorded presentation).
   - This ePoster with voiceover was distinct from the separate oral presentation based on the same poster.

By way of background, the abstract relating to the LUMIADE-3 clinical trial detailing the Phase III clinical trial results of the proposed biosimilar candidate FKS518 was submitted in October 2024 to the [congress organiser's] abstract portal and [congress organiser's] independent peer review process which would ensure content is of sufficient quality and scientific importance to be included as an ePoster as part of the official proceedings at the [named] congress on [date–date] April 2025 (the ***Congress****). The Congress is a prestigious scientific meeting, attended by more than 2000 in person HCP delegates and comprising over 70 sessions delivered by more than 200 expert speakers; including oral presentations and posters to allow for the dissemination of important scientific research from healthcare professionals, academia and also the pharmaceutical industry.*

Following acceptance of the aforementioned abstract the final version of the ePoster was submitted to the [congress organisers] by Fresenius Kabi as per the requisite timelines. The ePoster consisted of a four-slide digital PowerPoint presentation, being scientific in appearance as is typical of these types of materials, and in accordance with guidance issued by the [congress organisers].

As set out above, as is standard for these types of events, the ePoster was one of the approximately 200 that had been submitted by healthcare professionals, pharmaceutical companies and academia, that was made available for viewing on digital screens in the designated Poster Area. This Poster Area was physically separate from the commercial exhibition stands but on the same floor.

During the Congress, delegates were able to use the touch screens on one of the 28 official congress digital screens to scroll through or use filters to navigate to particular topics of interest. Delegates attending virtually were also able to access the ePoster

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(which included the voiceover) via the online Congress platform, which similarly required navigation or scrolling through the 200 ePosters and an additional 106 online only posters to view.

A Medical Science Liaison (MSL) was present during the designated poster discussion session allocated to Fresenius Kabi on [date], from 10:35 to 11:05, to respond to any scientific queries from individual attendees.

There was no separate oral presentation associated with this abstract or ePoster and the ePoster was not displayed anywhere other than the previously referred to platforms and screens provided by [the congress organisers] as part of the official congress proceedings.

2. A copy of the final version of the ePoster including either a transcript of the voiceover or a copy of the recording

The ePoster and transcript were approved following examination as two separate submissions. The original poster is [provided to the Panel] and there was a separate transcript [provided to the Panel].

3. Confirmation of whether the final version of the ePoster, including voiceover was certified or examined in accordance with the requirements of Clause 8 and its supplementary information and a copy of the relevant certificate

We can confirm that the final version of each of the ePoster and the transcript were examined separated by [details of medical signatory provided] in accordance with the requirements of Clause 8 and its supplementary information. Copies of the relevant proof of examination [provided to the Panel]. Given the ePoster and the transcript were not categorised as being promotional, certification was not necessary.

4. Details of how, when and where the ePoster was made available to view by conference delegates. – Did each ePoster have a dedicated screen or did they play on a rolling schedule or have dedicated timeslots? Or could users interact with the screen to manually select which poster they wanted to view?

As set out above the ePoster was available in the Poster Area and were viewed on a rolling basis. Users could also navigate to select which poster they wanted to review. There was a dedicated timeslot in which the ePoster was displayed and the MSL was available to answer questions as set out above in question 1.

5. How many members of the Fresenius Kabi Medical Team were present at the congress

There were two members of the Fresenius Kabi Medical Team present at the Congress. If a health professional had a question then the commercial team would have taken down details and this would have been passed to the MSL to answer as set out in the Briefing Document which is shared at Appendix 3.

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6. Details of whether medical information questions were received about the denosumab biosimilar or further conversation had by the medical staff in attendance at the congress

Medical Information request forms were available on the stand as set out in the Briefing Document. Any such requests would have been passed onto the Fresenius Kabi Medical Team at the Congress in accordance with the Briefing Document. There was the opportunity for congress delegates to ask questions during the poster session that would have been answered by the MSL and referred to the Medical Team if further information was deemed necessary to respond to individual requests as per the Briefing Document. Any such request forms would have been put onto the medical information database by the MSLs following the Congress in accordance with our standard processes. We have looked back records and there is no documentation that indicates any requests for information about FKS518 or denosumab."

PANEL RULING

This complaint was about an 'ePoster' presented at a rheumatology congress held in the UK in May 2025. The complainant alleged that the poster promoted Fresenius Kabi's biosimilar to denosumab, which had not yet received a marketing authorisation in the UK or EU.

Fresenius Kabi submitted that the ePoster at issue was a digital poster presentation of the LUMIADE-3 clinical trial which detailed the Phase III clinical trial results of FKS518, a proposed biosimilar candidate. It was an encore presentation of a poster (comprising the same clinical data) that had previously been presented by its Medical team at an international congress in the US in 2024.

The company's internal briefing document included, on a slide titled "Medical Activities, the following description of the poster:

> "Abstract submitted accepted for e-poster presentation at the Osteoporosis and Metabolic Bone showcase at a time TBC. To be presented by [redacted by Fresenius Kabi] [congress] Poster ID: P078. Poster is submitted electronically onto [congress organiser] abstract portal, with a voiceover. Poster is 4 slides, as per [congress organiser] template & is approved in Veeva (IE-NP-250002)".

From the information provided by Fresenius Kabi, the Panel understood that the ePoster was available to view on digital screens throughout the "Poster Zone" of the congress, which was physically separate from the commercial exhibition stands. Delegates could use the touch screens to navigate through the available posters and view those of interest. There was also a dedicated poster discussion session, during which a Fresenius Kabi Medical Scientific Liaison (MSL) was present to respond to any scientific queries from individual attendees. The congress briefing material described this poster discussion session as an oral presentation by a named speaker at the Osteoporosis and Metabolic Bone showcase. The ePoster was also available to delegates attending virtually via the online platform.

The ePoster consisted of four slides with a pre-recorded voiceover. The first slide read: "A Randomised, Controlled, Double-Blind Study to Evaluate the Bioequivalence of FKS518, A Proposed Biosimilar to Denosumab, with the Originator in Postmenopausal Women with Osteoporosis. LUMIADE-3 STUDY". The remaining three slides presented the objectives,

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background and study design, results including therapeutic equivalence, efficacy and safety, and conclusions. The first and final slides included the prominent statement “Come see us at Stand 26” in the bottom left-hand corner of the slide, and the Fresenius logo in the right-hand corner.

While noting that the ePoster had been submitted to and accepted by the conference organisers, the Panel considered that the organising committee would be looking at content in terms of scientific robustness but not in terms of its compliance with the Code. Fresenius Kabi had not argued that the poster presentation was outside the scope of the Code and, further, had examined the poster indicating that it took responsibility for the material under the Code. The Panel acknowledged that poster presentations at medical congresses were a long-standing and legitimate activity.

Clauses 3.1 and 11.1

In response to the complainant’s allegation that the ePoster promoted Fresenius Kabi’s denosumab biosimilar prior to the grant of its marketing authorisation, Fresenius Kabi submitted that the Code did not prohibit the non-promotional dissemination of scientific information, including clinical trial data, when conducted in a responsible, factual, and balanced manner. Fresenius Kabi submitted that the activity was a “legitimate exchange of medical and scientific information during the development of a medicine”, as permitted by the supplementary information to Clause 3.1, and that it was presented in a scientific forum to a professional audience, with the sole intent of contributing to the scientific discourse and advancing medical knowledge. Fresenius Kabi submitted that the ePoster contained purely scientific, factual and non-promotional information; it was clearly framed as scientific, data presented was accurate, fair, balanced, and capable of substantiation, and no claims were made that extended beyond the data. Fresenius Kabi submitted that the ePoster included an explicit disclaimer that FKS518 was a “proposed biosimilar” rather than an approved medicinal product.

The Panel disagreed with Fresenius Kabi’s submission that the ePoster included an “explicit disclaimer” that FKS518 was a proposed biosimilar rather than an approved medicinal product. While the ePoster described FKS518 as a “proposed biosimilar”, there was no “disclaimer” statement or explanation that this meant that the medicine was unlicensed.

Clauses 3.1 and 11.1 prohibit the promotion of a medicine prior to the grant of its marketing authorisation. The supplementary information to Clause 3.1 states that the legitimate exchange of medical and scientific information during the development of a medicine is not prohibited, provided that any such information or activity does not constitute promotion which is prohibited under this or any other clause. The Panel considered that the context in which the exchange took place, the development stage of the medicine and the audience would be important factors in determining whether the activity was acceptable under the Code. In this regard, the Panel noted that the legitimate exchange of scientific information during the development of a medicine should involve debate in which delegates could actively participate and that enhanced the current state of scientific knowledge and that it should not be a one-way flow of information. The Panel queried whether Phase 3 data which showed equivalence between a biosimilar and its originator product was appropriate material for such a debate. Further, it appeared likely that delegates would view the ePoster alone, at a congress terminal, or remotely. PMCPA guidance on Clauses 3.1 and 11.1 in addition stated that there should be no connection or overarching theme between the promotional and non-promotional activities at a congress and further that if a

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marketing authorisation had been applied for in any country the medicine was unlikely to be seen as still 'in development'.

The Panel noted that while the proposed biosimilar was still referred to by its internal product identifier, the Phase III study had completed and that the marketing authorisation application was under review by the EMA. The Panel therefore considered that the proposed biosimilar, FKS518, could be considered an unlicensed medicine for the purposes of the Code and was not still "in development".

From the information before the Panel, it did not appear that the ePoster would enable delegates to participate in discussion. In addition to the points above, due to the format of the ePoster with voiceover and its availability to be viewed throughout the duration of the congress it did not appear to the Panel that the arrangements enabled discussion and debate – it appeared to be a one-way flow of information. The Panel determined that Fresenius Kabi had not demonstrated that the ePoster satisfied the requirements for the legitimate exchange of medical and scientific information during the development of a medicine. The complainant had not referred to the oral presentation at the Osteoporosis and Metabolic showcase (mentioned in the company's briefing material) in their complaint and the Panel made no comment on this aspect of Fresenius Kabi's presence at the congress.

The Panel then had to consider whether the ePoster and arrangements were promotional.

In the Panel's view, the inclusion of the prominent statement "Come see us at Stand 26" on the first and fourth slides was likely to solicit questions about the content of the ePoster – i.e. about the unlicensed medicine, FKS518. The statement was in same font colour as the slide subheadings, and the main clinical claim on the final slide. In the Panel's view it was difficult to see the statement as anything other than an invitation to discuss the content of the slides at the main exhibition stand. Fresenius Kabi acknowledged that the phrase would facilitate professional engagement at a scientific congress. The Panel noted that, while the exhibition stand did not contain information about FKS518, it was a promotional stand for Fresenius Kabi's licensed ustekinumab and tocilizumab biosimilars.

The briefing document for staff included three congress objectives, one of which was to "raise awareness of the biosimilars portfolio with key rheumatology stakeholders". The Panel considered that the evidence did not support Fresenius Kabi's submission in relation to dealing with questions received about its denosumab biosimilar at the exhibition stand, that "Medical Information request forms were available on the stand as set out in the Briefing Document" and "any such requests would have been passed onto the Fresenius Kabi Medical Team at the Congress in accordance with the Briefing Document". Further, Fresenius Kabi submitted that such requests would be referred to onsite MSLs **or** recorded as a medical information request – it therefore appeared to the Panel that not all requests were recorded. The briefing document contained no specific guidance for staff on what to do if they received a question about FKS518. The only mention of the medical information request form within the briefing slides in the context of a specific medicine was in relation to Otulfi (ustekinumab) which had a marketing authorisation. The slide headed 'Commercial Content' referred to three materials including a medical information request form which was described as an insight gathering tool and to "pass on information requests to the relevant MSL". While the slide headed 'Medical Activities' did refer to the poster and 'oral presentation' and gave the ePoster's full title, there was no guidance on that slide or elsewhere in the briefing about how to satisfy the requirements of the Code in relation to unlicensed medicines and congresses and the denosumab biosimilar in particular. In

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the Panel's view, this was wholly unsatisfactory given the ePoster about an unlicensed medicine invited delegates to visit the promotional stand.

Taking into account the content of the ePoster at issue, which included safety and efficacy results from the Phase III study and a statement encouraging the reader to visit the company's promotional exhibition stand, the Panel considered that the ePoster was soliciting questions about an unlicensed medicine and, in addition, company staff at the promotional stand were inadequately briefed about how to deal with such requests in accordance with the Code. The arrangements were promotional for the unlicensed medicine, FKS518 and therefore the ePoster was in **breach of Clauses 3.1 and 11.1**.

Clauses 12.1 and 8.1

The complainant alleged a breach of Clause 12.1 because the ePoster did not contain prescribing information. While the Panel considered that the arrangements and ePoster were promotional, it acknowledged that, as the medicine was unlicensed, it was not possible to include prescribing information. The Panel considered that the ePoster could therefore not fulfil the requirements of Clause 12.1 and so the **Panel made no ruling in this regard**.

The complainant alleged that the ePoster did not include a visible job code, approval statement, or certification marking and questioned whether it had been properly reviewed and approved prior to dissemination, as required by Clause 8.1.

Fresenius Kabi submitted that the final version of the ePoster and the transcript of the voiceover were each examined separately in accordance with the requirements of Clause 8; however, as they were not categorised as promotional, they had not been certified.

The Panel had determined, above, that the ePoster was promotional for an unlicensed medicine, which was not permitted under the Code which reflected UK legal requirements on this point. The Panel considered, therefore, that it would not have been possible for the ePoster to have been certified as being in accordance with the relevant regulations relating to advertising and the Code, and that it was not inconsistent with its marketing authorisation. The Panel therefore **made no ruling in this regard**.

Clauses 5.1 and 2

The complainant alleged that:

- The use of a prescriber-focused scientific congress as a platform to share near-launch data on an unlicensed medicine demonstrated poor judgement by Fresenius Kabi
- There was a risk that health professionals might interpret this information as a signal of imminent availability or regulatory endorsement, which could lead to misleading clinical assumptions
- The lack of restraint in timing, tone, and messaging undermined trust in the responsible conduct of pharmaceutical companies
- The conduct appeared to be part of a coordinated pre-launch promotional strategy.

The Panel considered that as a general principle it was not inappropriate for non-promotional information about Phase III studies to be presented as a poster presentation at scientific congresses.

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The Panel considered that, by linking the ePoster about Phase III results of an unlicensed medicine to the company's promotional exhibition stand, and by failing to demonstrate sufficient briefing of staff in relation to FKS518, Fresenius Kabi had failed to maintain high standards. The Panel ruled a **breach of Clause 5.1**.

While promotion prior to the grant of a marketing authorisation was an example of an activity likely to be ruled in breach of Clause 2, the Panel took into account the particular circumstances of this case. The Panel considered that there was no evidence to support the complainant's allegation that this ePoster was part of a "coordinated pre-launch promotional strategy" and took into account that the ePoster was available in the Poster Zone of a genuine scientific congress. On balance, the Panel did not consider that the circumstances of this case were such that Fresenius Kabi had brought discredit upon, or reduced confidence in, the pharmaceutical industry. The ruling of a breach of Clause 5.1 was sufficient to address the Panel's concerns and the Panel therefore ruled **no breach of Clause 2**.

1. Simple bullet points

- First item
- Second item
- Third item

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2. Nested bullet points (2 levels)

- Fruits
  - Apple
  - Banana
  - Orange
- Vegetables
  - Carrot
  - Broccoli
  - Spinach

---

3. Multi-level nested bullet points (3–4 levels)

- Continent
  - Country
    - State / Province
      - City
        - District
- Project Alpha
  - Phase 1: Discovery
    - Task A
      - Subtask A1
      - Subtask A2
    - Task B
  - Phase 2: Delivery
    - Task C
      - Subtask C1
        - Sub-subtask C1.1
        - Sub-subtask C1.2
    - Task D

---

4. Numbered lists

4a. Flat

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1. First step
2. Second step
3. Third step

4b. Nested numbered

1. Setup
    1. Install dependencies
    2. Configure environment
2. Execution
    1. Run tests
    2. Review results
3. Teardown

4c. Numbered list not starting at 1

5. Fifth item (list starts at 5)
6. Sixth item
7. Seventh item

4d. Mixed numbered + bullet nesting

1. Preparation
    - Gather requirements
    - Assign owners
2. Development
    - Backend
        - API design
        - Database schema
    - Frontend
        - Component library
        - State management

5a. Dash-based

- Task one
- Task two
- Task three

5b. Asterisk-based

- Red
- Green
- Blue

5c. Plus-based

- One
- Two
- Three

5d. Alphabetic ordered

a. First option b. Second option c. Third option

5e. Roman numeral ordered

i. Introduction ii. Methodology iii. Results iv. Conclusion

5f. Tick / checkbox (task) lists

- Unchecked task
- Completed task (lowercase x)
- Completed task (uppercase X)
- Another pending task
    - Nested subtask, unchecked

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    - Nested subtask, completed

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6. Combined stress test

1. Epic: Checkout Flow
    - Cart page
        - Add item to cart
        - Remove item from cart
    - Payment page

1. Validate card details
2. Process payment
        - Success state
        - Failure state

2. Epic: User Profile
    - Settings
        - Notifications
        - Privacy
    - Avatar upload
        - Crop tool
        - Filters

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7. Edge cases

- A single bullet with a very long line of text that should wrap onto a second visual line without breaking the list item structure or creating a new bullet, so the renderer's line-wrap handling can be checked independently of its list-nesting handling.
- Item with **bold**, *italic*, and inline code inside a bullet
    - Nested item with a link inside it
- Empty-looking item below (contains only a space):
-

1. Numbered item followed directly by a bullet list with no blank line between them
- Bullet right after a numbered item

Complaint received **25 June 2025**

Case completed **31 March 2026**

Sensitivity: General